DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

February 26,2015

Kuraray Noritake Dental, Inc.
Michio Takigawa
Manager
Ote Center Bldg. 7f, 1-1-3, Otemachi
Chiyoda Ku, Tokyo 100-0004 Japan

Re: K142623
Trade/Device Name: Panavia SA Cement Plus Handmix
Regulation Number: 21 CFR 872.3275
Regulation Name: Dental Cement
Regulatory Class: Class II
Product Code: EMA
Dated: January 23, 2015
Received: January 26, 2015

Dear Mr. Takigawa,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin Keith
Director
Division of Anesthesiology,
General Hospital, Respiratory, Infection
Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K142623

Device Name: PANAVIA SA Cement Plus Handmix

Indications for Use:

[1] Cementation of crowns, bridges, inlays and onlays

[2] Cementation of prosthetic restorations on implant abutments and frames

[3] Cementation of adhesion bridges and splints

[4] Cementation of posts and cores

[5] Amalgam bonding

Prescription Use ✓ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use N/A (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Date: February 25 ,2015

510(k) Summary

3-1. 510(k) owner (submitter)

1) Name	Kuraray Noritake Dental Inc.
2) Address	1621 Sakazu, Kurashiki, Okayama 710-0801, Japan
3) Contact person	Michio Takigawa Quality Assurance Department
4) Contact person in US	Goro Asanuma KURARAY AMERICA, INC. 33 Maiden Lane, 6th Floor, New York, NY 10038 Tel: (212)-986-2230 (Ext. 115) or (800)-879-1676 Fax: (212)-867-3543

3-2. Name of Device

1) Trade / Proprietary name	PANAVIA SA Cement Plus Handmix
2) Classification name	Dental cement (21 CFR section 872.3275. Product code: EMA)
3) Common name	Dental adhesive resin cement

3-3. Predicate devices

1) PANAVIA SA CEMENT Handmix	510(k) Number	K120378
	Classification:	Dental cement
	Product Code:	EMA
	21 CFR Section:	872.3275
	Applicant:	Kuraray Noritake Dental Inc.
2) PANAVIA F 2.0	510(k) Number:	K032455
	Classification:	Dental cement
	Product Code:	EMA
	21 CFR Section:	872.3275
	Applicant:	Kuraray Noritake Dental Inc.
3) CLEARFIL AP-X	510(k) Number:	K012740
	Classification:	Tooth shade resin material
	Product Code:	EBF
	21 CFR Section:	872.3690
	Applicant:	Kuraray Noritake Dental Inc.
4) CLEARFIL TRI-S BOND	510(k) Number:	K042913
	Classification:	Resin tooth bonding agent
	Product Code:	KLE
	21 CFR Section:	872.3200
	Applicant:	Kuraray Noritake Dental Inc.
5) CLEARFIL DC CORE PLUS	510(k) Number:	K111982
	Classification:	Tooth shade resin material
	Product Code:	EBF
	21 CFR Section:	872.3690
	Applicant:	Kuraray Noritake Dental Inc.

3-4. Device Description

The subject device is a dual-cure (light- and/or self-cure), fluoride releasing, radiopaque self-adhesive resin cement for ceramic (porcelain, lithium disilicate, zirconia, etc.), composite resin, and metal restorations.
This is the new registration application for the subject device and there have not been any prior submissions regarding the subject device.

3-5. Statement of Intended Use

The subject device is indicated for the following uses:
[1] Cementation of crowns, bridges, inlays and onlays
[2] Cementation of prosthetic restorations on implant abutments and frames
[3] Cementation of adhesion bridges and splints
[4] Cementation of posts and cores
[5] Amalgam bonding

3-6. Substantial Equivalence Discussion

1) Intended uses

The INDICATIONS of the subject device and predicate devices, PANAVIA SA CEMENT Handmix which is self-adhesive resin cement and PANAVIA F2.0 which is dental resin cement, are as listed on the following table.

	Trade name	Intended use
Subject device	PANAVIA SA Cement Plus Handmix	[1] Cementation of crowns, bridges, inlays and onlays [2] Cementation of prosthetic restorations on implant abutments and frames [3] Cementation of adhesion bridges and splints [4] Cementation of posts and cores [5] Amalgam bonding
Predicate devices	PANAVIA SA CEMENT Handmix	[1] Cementation of crowns, bridges, inlays and onlays made of porcelain, ceramic, composite resin or metal [2] Cementation of porcelain, ceramic, composite resin or metal restorations on implant abutments [3] Cementation of metal cores, resin cores, metal posts or glass fiber posts
	PANAVIA F2.0	[1] Cementation of metal crowns and bridges, inlays and onlays [2] Cementation of porcelain crowns, inlays, onlays and veneers [3] Cementation of composite resin crowns, inlays, and onlays [4] Cementation of adhesion bridges [5] Cementation of endodontic cores and prefabricated posts [6] Amalgam bonding

The intended use of the subject device was written up based on those of the predicate devices. Therefore, the intended use of the subject device is substantially equivalent to those of the predicate devices.

2) Chemical ingredients/ Safety

Except for 5 chemical ingredients, all ingredients in the subject device have been used in the predicate devices. Regarding the predicate devices, there have not been any reported problems or recalls according to the post market adverse event reporting requirements in the US.
The subject device contains new 5 ingredients. Therefore, we evaluated the subject device referring to ISO 10993 series and ISO 7405. As a result of the tests, it was concluded that the subject device is substantially equivalent in biological safety to the predicate device.

3) Technological characteristics/ Effectiveness and Performance

Physical and mechanical properties of the subject device were evaluated according to ISO 4049: 2009 (Dentistry - Polymer-based restorative and materials).

The results of comparative study performed according to ISO 4049: 2009 were indicated below.

Section		PANAVIA SA Cement Plus Handmix (Subject device)		PANAVIA SA CEMENT Handmix (Predicate device)	
		Shade type: Universal, Translucent	Shade type : White	Shade type: Universal (A2)	Shade type : White
5.2.2 Film thickness, luting materials		***COMPLIES***	***COMPLIES***	***COMPLIES***	***COMPLIES***
5.2.4 Working time, Class 1 and Class 3 luting materials		***COMPLIES***	***COMPLIES***	***COMPLIES***	***COMPLIES***
5.2.6 Setting time, Class 3 materials		***COMPLIES***	***COMPLIES***	***COMPLIES***	***COMPLIES***
5.2.9 Flexural strength		***COMPLIES***	***COMPLIES***	***COMPLIES***	***COMPLIES***
5.2.10 Water sorption and solubility	*Water sorption*	***COMPLIES***	***COMPLIES***	***COMPLIES***	***COMPLIES)***
	Solubility	***COMPLIES***	***COMPLIES***	***COMPLIES***	***COMPLIES***
5.4 Color stability after irradiation and water sorption		***COMPLIES***	***COMPLIES***	***COMPLIES***	***COMPLIES***
5.5 Radio-opacity		***COMPLIES***	***COMPLIES***	***COMPLIES***	***COMPLIES***

The results indicate that the subject device and the predicate device comply with the requirements of ISO 4049: 2009. From the above, it can be said that comparative study of the subject device is substantially equivalent to that of the predicate device.

Tensile bond strength to bovine dentin was evaluated in accordance with ISO/TS 11405: 2003.
The result of the subject device is shown on the following table.

Adherend	Criteria	PANAVIA SA Cement Plus Handmix (Subject device)	PANAVIA SA CEMENT Handmix (Predicate device)
Bovine dentin	In-house standard	***COMPLIES***	***COMPLIES***

It was confirmed that there were no statistically ($p>0.05$) significant differences between the subject device and the predicate device.
Therefore, it was concluded that tensile bond strength to bovine dentine of the subject device is substantially equivalent to that of the predicate device.

Shear bond strength to the implant abutment was evaluated in accordance with ISO/TS 11405: 2003.
The result of the subject device is shown on the following table.

Adherend	Criteria	PANAVIA SA Cement Plus Handmix (Subject device)	PANAVIA SA CEMENT Handmix (Predicate device)
Titan 100	In-house standard	***COMPLIES***	***COMPLIES***

It was confirmed that there were no statistically ($p>0.05$) significant differences between the subject device and the predicate device.
Therefore, it was concluded that shear bond strength to the implant abutment of the subject device is substantially equivalent to that of the predicate device

Released fluorine ion test was performed to validate the substantial equivalence of the subject device with the predicate device in terms of effectiveness and performance for the intended uses.
It was concluded that amount of released fluorine ion from the subject device is substantially equivalent to those from the predicate device.

3-7. Biocompatibility

The subject device is classified according to ISO 7405:2008 and ISO 10993-1:2009 as an external communicating device that will have permanent (> 30 days) contact with tissues. We performed the biological safety tests of PANAVIA SA Cement Plus Automix which is a similar composition. As a result of the tests, it was concluded that the subject device is substantially equivalent in biological safety to the predicate device.

3-8. Conclusion

The comparison for intended uses, chemical ingredients/ safety and performance data shows that the subject device is substantially equivalent to the predicate devices.
This submission information including the nonclinical testing provided supports that the subject device is as safe and as effective as the predicate devices.